Regenerative Medicine Consortium reference material

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The following documents and websites provide reference material about FDA and NIH regulation of regenerative medicine.

- Pre-IND meetings
- Past presentations
- FDA website links
- Guidance documents
- Advisory committee documents
- Miscelaneous

Go back to the Regenerative Medicine Consortium

Pre-IND meetings

For information about pre-IND meetings as well as other types of regulatory meetings with the FDA, please see the following documents:

- Formal Meetings with Sponsors and Applicants for PDUFA Products [pdf]
- SOPP 8101.1: Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Application

Interested parties may contact Dr. Patrick Riggins, Ph.D., Branch Chief, Regulatory Management Staff, at 301-827-5366, or Patrick.Riggins@fda.hhs.gov for any questions related to early meetings, pre-IND meetings or other types of regulatory meetings with OCTGT.

Past Presentations

- April 15 Webinar: Issues in Product Characterization
- CMC Considerations for Stem Cell-based Products [ppt]
- Preclinical Considerations for Stem Cell-Based Products [ppt]
- FDA Oversight of Cell Therapy Clinical Trials

FDA & NIH Website Links

- NIH Stem Cell Interest Group
- CBER webpage
- CBER Guidance Documents
- CBER Standard Operating Procedure and Policy Documents
- CBER Biologics Rules
- References for the Regulatory Process for the Office of Cellular, Tissue and Gene Therapies
- Tissue Proposed and Final Rules
- Cell Therapy and Gene Therapy Advisory Committee
- Information about Cell and Gene Therapy Products
- Information about Tissue and Tissue-Based Products
- Information about xenotransplantation

- FDA Transparency Task Force
- FDA Basics

Guidance documents

- Draft Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products (11/12)
- Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products (1/11)
- Draft Guidance for Industry: Somatic Cell Therapy for Cardiac Disease (10/10)
- Draft Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (1/09)
- ISSCR Guidelines for the Clinical Translation of Stem Cells [pdf] (12/03/08)
- Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs) (4/08)
- Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug applications (INDs) (4/08)
- Draft Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products (2/08)
- Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide (8/07)
- Guidance for Industry: Gene Therapy Clinical Trials-Observing Participants for Delayed Adverse Events (11/06)
- Guidance for Industry: Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements (9/06)
- Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (5/05)
- Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans (4/03)
- Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts (2/02)
- Guidance for Industry: Public Health Issues Posed by the Use of Non-Human Primate Xenografts in Humans (4/99)
- Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy (3/98)

Advisory committee documents

- Documents from May 14-15, 2009 AC meeting
- Link Documents from July 13, 2000 AC meeting on Stem Cells (from this link, associated documents are found under the 7/13 and 7/14 Biological Response Modifiers Advisory Committee Meeting)

Miscellaneous

- 1993 Federal Register Notice on Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene The [pdf]
- 1997 Proposed Approach to Regulation of Cellular and Tissue-Based Products [pdf]
- PHS Guideline on Infectious Disease Issues in Xenotransplantation

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